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Using reduced amounts of cyclosporin A, as in Composition II, to achieve therapeutic effectiveness mitigates even further against undesirable side effects and potential drug interactions. Prescribing physicians can provide (prescribe) Composition II to more patients and/or with fewer restrictions and/or with reduced risk of the occurrence of adverse events, e.g., side effects, drug interactions and the like, relative to providing Composition I.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.

What is claimed is:

1. A method of increasing tear production in the eye of a human, the method comprising topically administering to the eye of the human in need thereof an emulsion at a frequency of twice a day, wherein the emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil in an amount of about 1.25% by weight; and wherein the topical ophthalmic emulsion is effective in increasing tear production.

2. The method of claim 1, wherein the emulsion further comprises a tonicity agent or a demulcent component.

3. The method of claim 2, wherein the tonicity agent or the demulcent component is glycerine.

4. The method of claim 1, wherein the emulsion further comprises a buffer.

5. The method of claim 4, wherein the buffer is sodium hydroxide.

6. The method of claim 1, wherein the topical ophthalmic emulsion further comprises glycerine and a buffer.

7. The method of claim 1, wherein the emulsion comprises polysorbate 80 in an amount of about 1.0% by weight.

8. The method of claim 1, wherein the emulsion comprises acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight.

9. The method of claim 1, wherein the emulsion further comprises glycerine in an amount of about 2.2% by weight and a buffer.

10. The method of claim 9, wherein the buffer is sodium hydroxide.

11. The method of claim 1, wherein, when the emulsion is administered to an eye of a human in an effective amount in increasing tear production, the blood of the human has substantially no detectable concentration of cyclosporin A.

12. The method of claim 6, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.

13. The method of claim 1, wherein the emulsion is as substantially therapeutically effective as a second emulsion administered to a human in need thereof at a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

14. The method of claim 1, wherein the emulsion achieves at least as much therapeutic effectiveness as a second emulsion administered to a human in need thereof at a frequency of

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twice a day, the second emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

15. The method of claim 1, wherein the emulsion breaks down more quickly in the eye of a human, once administered to the eye of the human, thereby reducing vision distortion in the eye of the human as compared to a second emulsion that contains only 50% as much castor oil.

16. The method of claim 1, wherein the emulsion, when administered to the eye of a human, demonstrates a reduction in adverse events in the human, relative to a second emulsion administered to a human in need thereof at a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

17. The method of claim 16, wherein the adverse events are side effects.

18. A method of treating keratoconjunctivitis sicca, the method comprising the step of topically administering to an eye of a human in need thereof an emulsion at a frequency of twice a day, the emulsion comprising:

cyclosporin A in an amount of about 0.05% by weight;
castor oil in an amount of about 1.25% by weight;
polysorbate 80 in an amount of about 1.0% by weight;
acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight;
a tonicity component or a demulcent component in an amount of about 2.2% by weight;
a buffer; and
water;

wherein the emulsion is effective in treating keratoconjunctivitis sicca and wherein the topical ophthalmic emulsion has a pH in the range of about 7.2 to about 7.6.

19. The method of claim 8, wherein the buffer is sodium hydroxide.

20. The method of claim 8, wherein the tonicity component or the demulcent component is glycerine.

21. The method of claim 8, wherein, when the emulsion is administered to the eye of a human in an effective amount in treating keratoconjunctivitis sicca, the blood of the human has substantially no detectable concentration of the cyclosporin A.

22. A method comprising:

administering an emulsion topically to the eye of a human having keratoconjunctivitis sicca at a frequency of twice a day, wherein the emulsion comprises:

cyclosporin A in an amount of about 0.05% by weight;
castor oil in an amount of about 1.25% by weight;
polysorbate 80 in an amount of about 1.0% by weight;
acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight;
glycerine in an amount of about 2.2% by weight;
sodium hydroxide; and
water; and

wherein the emulsion is effective in increasing tear production in the human having keratoconjunctivitis sicca.

23. The method of claim 22, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.

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